4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA-2011-N-0920]

RIN 0910-AG36

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Extension of Comment Periods

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period for the proposed rule and for its information collection provisions.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice of proposed rulemaking that appeared in the Federal Register of January 16, 2013 (78 FR 3646), entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" and its information collection provisions.

DATES: The FDA is extending the comment period for the proposed rule referenced in the Summary. Submit either electronic or written comments on the notice of proposed rulemaking by November 22, 2013. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by November 22, 2013 (see the "Paperwork Reduction Act of 1995" section).

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0920 and/or Regulatory Information Number (RIN) 0910-AG36, by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office

of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2011-N-0920, and RIN 0910-AG36 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "How to Submit Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: With regard to the proposed rule: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2166. With regard to the information

collection: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, domini.bean@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 16, 2013 (78 FR 3646), FDA published a proposed rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food." The original comment period of 120 days was extended several times and interested persons were most recently given until November 15, 2013 (Federal Register of August 9, 2013, 78 FR 48636), to comment on the proposed rule and its information collection provisions.

II. Request for Comments

FDA is extending the comment period due to the inability of some commenters to submit comments through the http://www.regulations.gov Web site from November 4, 2013, through November 14, 2013, because of technical difficulties at that Web site.

III. Paperwork Reduction Act of 1995

Interested persons may either submit electronic comments regarding the information collection to oira_submission@omb.eop.gov or fax written comments to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285. All comments should be identified with the title "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food."

IV. How to Submit Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see

ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: November 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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